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<p>(21) International Application Number: PCT/US00/00625 (22) International Filing Date: 11 January 2000 (11.01.00) (30) Priority Data: 60/115,583 12 January 1999 (12.01.99) US (71) Applicants: GAMBRO, INC. [US/US]; Patent Department, 10810 Collins Ave., Lakewood, CO 80215 (US). HOSPAL INDUSTRIE [FR/FR]; Patent Department, 7 Avenue Linel Terray, F-69883 Meyzieu Cedex (FR). (72) Inventors: FRESSINET, Jean-Louis; Les Hautes Bruyeres, F-69700 St. Jean De Touslas (FR). LITTLE, James, S., Jr.; 427 Brookside Drive, Bailey, CO 80421 (US). GREENE, David, B.; 13722 W. Juan Drive, Lakewood, CO 80228 (US). FRUGIER, Alain; 89 Avenue Du Grand Paradis, F-38230 Tignieu (FR). (74) Agents: WINSOR, Bruce, R. et al.; Patent Department, 10810 Collins Avenue, Lakewood, CO 80215 (US).</p>		<p>(81) Designated States: CA, JP, MX, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  Published With international search report.</p>
<p>(54) Title: CONTINUOUS RENAL REPLACEMENT THERAPY HEAT LOSS COMPENSATION</p> <p>(57) Abstract</p> <p>An integrated CRRT method and apparatus (10) incorporates steps and means for compensating for heat loss from blood in an extracorporeal circuit. A blood warmer (20) is designed to engage and hold a disposable blood tube segment to transfer heat at a closely controlled temperature to blood flowing in the disposable blood tube segment. Another significant aspect of the present invention is a blood tube segment for engagement with the blood warmer (20) is located in downstream of a dialyzer and upstream of a venous pressure monitor (15), an air bubble detector (90) and a venous line clamp (95). The disposable blood tube segment may be selectively connected when heat loss compensation is required and left disconnected when heat loss compensation is not required.</p>		

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**CONTINUOUS RENAL REPLACEMENT THERAPY HEAT LOSS  
COMPENSATION**

5

**RELATED APPLICATIONS**

This application claims the priority of United States Provisional Patent Application  
10 No. 60/115,583 filed January 12, 1999.

**TECHNICAL FIELD**

The invention relates to a method and apparatus for continuous renal replacement  
15 therapy. More particularly, this invention relates to a method and apparatus for  
compensating for extracorporeal heat loss from a patient undergoing continuous renal  
replacement therapy.

**BACKGROUND**

20

When a patient experiences renal failure, one of several extracorporeal blood  
treatment processes may be performed in order to replace the function of the failed kidneys.  
The processes include, without limitation, dialysis, ultrafiltration, hemofiltration, and  
hemodiafiltration, all of which, and similar processes, will be referred to herein collectively  
25 as "dialysis." Further "dialyzer" as used herein will be understood to mean a dialyzer,  
hemofilter or similar device. In the event of chronic, or permanent, kidney failure, also

known as end stage renal disease, or ESRD, dialysis is usually performed at relatively high blood flow rates for around three or four hours, typically thrice per week. This type of periodic treatment challenges the patient's body, but is well tolerated by most ESRD patients as it offers them the opportunity for a relatively normal life.

5           Acute kidney failure, from which a patient may, in time, recover is often accompanied by other injuries or underlying disease which render the patient's body unable to withstand the rigors of periodic dialysis. These acute patients are usually treated at relatively lower blood flow rates and treated continuously. Also, very young patients are often unable to withstand the rigors of periodic dialysis and are often treated at low blood  
10   flow rate and/or continuously. This form of dialysis will be referred to herein as continuous renal replacement therapy or CRRT.

          A method and apparatus for CRRT including equipment and disposable elements, is described in U.S. Patents No. 5,394,732, 5,441,363 and 5,676,245 which are incorporated herein in their entirety by reference. Further, an apparatus for performing CRRT is sold by  
15   affiliates of the assignee of the present application under the tradename PRISMA™.

          In dialysis some heat is generally lost to the environment from the blood circulating in the extracorporeal circuit, which, in time, results in loss of heat from the patient's body. In periodic treatment, the body's metabolic processes usually compensate for this heat loss and the patient's corporeal temperature is not significantly depressed. The continuous nature  
20   of CRRT increases the heat loss potential of the blood circulating in the extracorporeal circuit and the patient may, under certain circumstances, experience a depression of corporeal temperature.

          It is, therefore, desirable, in some CRRT treatments, to compensate for heat loss from the patient's blood circulating extracorporeally. Fluid heaters have been used to heat either  
25   dialysate or infusate fluid. Typical blood flow rate in CRRT is approximately 120 ml/min

**DETAILED DESCRIPTION OF THE PREFERRED EQUIPMENT**

A presently preferred embodiment of the present invention will be described with reference to Figures 1-5. It will be understood by those skilled in the art that the present invention is not limited to the presently preferred embodiment but encompasses such variations as are apparent to one having skill in the art.

A continuous renal replacement therapy apparatus (CRRT) 10 in accordance with the present invention is illustrated in Figure 1. The CRRT apparatus 10 comprises a CRRT monitor 15 and a blood warmer 20. The CRRT monitor 15 is preferably a PRISMA™ CRRT apparatus as sold by affiliates of the assignee of the present invention or the apparatus as generally described in U.S. Patents No. 5,934,732, 5,441,363 and 5,676,245. The blood warmer 20 is preferably a Stihler model number 9662032 fluid warmer comprising a heat exchanger section 25 and a control section 30 and having an electric heat element internally disposed (not shown) and in thermal communication with the heat exchange section 25. The principles of operation of the blood warmer 20 are described in U.S. Patent No. 4,709,135 which is incorporated herein in its entirety by reference. The electric heater of the blood warmer 20 is an ac heater rated at approximately 400 watts. The blood warmer 20 is mounted to one side of the CRRT monitor 15 by any suitable means, such as a bracket or handle mount.

Referring to Figure 2, a dialysis disposable tubing set 35 comprises an assembly of flexible medical tubes, peristaltic pump headers, a dialyzer, solutions, pressure pods, and sample access sites all assembled into a configuration as necessary to facilitate performing dialysis as that term is defined herein. The dialysis disposable tubing set 35 is mounted to the CRRT monitor 15 as illustrated in Figure 2. A further description of a dialysis disposable tubing set 35 of the prior art, which may be adapted for use with the present

invention, is included in U.S. Patent No. 5,441,363 and 5,676,245. In pertinent part, the dialysis disposable tubing set 35 comprises a dialyzer 40 which, as stated above, may be a dialyzer or a hemofilter. A first venous line 45 is connected to the dialyzer and terminates in a first female luer connector 50. The first female luer connector 50 is connected to and in  
5 fluid communication with a first male luer connector 55. A second venous line 60 connects the first male luer connector 55 to a sample access site 65. A third venous line 70 interconnects the sample access site 65 with a pressure monitoring pod 75. The pressure monitoring pod 75 interconnects and cooperates with a venous pressure transducer 80 (Figure 1) to transmit pressure occurring in the venous blood lines 70, 85 to the pressure  
10 transducer 80 which is a portion of the CRRT monitor 15. A fourth venous line 85 interconnects the pressure monitoring pod 75 with a return catheter (not shown), which is, in turn, connected to the patient to return treated blood to the patient. The fourth venous line 85 is threaded through an ultrasonic air bubble detector (UABD) 90, which serves as an air embolism protection detector, and, following the UABD 90, a venous clamp 95. The blood  
15 warmer 20 is illustrated in Figure 2 as physically separate from the CRRT monitor 15 for clarity but it is, of course, physically mounted to the CRRT monitor 15 as described above.

The UABD 90 is advantageously an ultrasonic air bubble detector as described in U.S. Patent No. 5,934,732. When it is not desired to compensate for heat loss in the extracorporeal blood circuit, the first female luer 50 is connected to, or remains connected to,  
20 the first male luer connector 55 as illustrated in Figure 2. The UABD 90 and the venous clamp 95 interact with the fourth venous line 85 to detect air bubbles in the fourth venous line 85 and, upon detection of air bubbles in the fourth venous line 85 by the UABD 90, to close the venous clamp 95 in order to protect the patient from infusion of air bubbles or an air embolism, which can have a deleterious effect on the patient.

75 will continue to be indicative of the true venous pressure at the patient and will be unaffected by the pressure loss in the extension line 100.

Figures 4 and 5 illustrate loading the extension line 100 into the blood warmer 20. The alignment marker tape 115 is placed under a front tubing clip, 120, of the blood warmer 20. The heat exchanger section 25 of the blood warmer 20 comprises an external cylindrical surface having a helical groove (not shown) running from a front end of the heat exchanger section 25 to the rear end. The helical groove has a generally semicircular cross section which mates with and accepts tubing of the outside diameter of the extension line 100. The extension line 100 is wound helically into the helical slot from the front end of the heat exchanger section 25 to the rear end and secured under a rear tubing clip 123. In the preferred embodiment, the extension line 100 makes nine helical turns about the heat exchanger section 25. Once the extension line 100 has been installed in the helical groove, a clam-shell thermal sleeve 125 is installed over the heat exchange section to hold the extension line 100 in place and to improve the heat transfer characteristics from the heat exchange section 25 to the extension line 100.

In the preferred embodiment, a bracket 150 which mounts the blood warmer 20 to the CRRT monitor 15 is a swivel mount which permits swiveling the blood warmer 20 away from the CRRT monitor 15 for installation of the extension line 100 and clam-shell thermal sleeve 125 and swiveling the blood warmer 20 back to a more convenient operating and connection position once the extension line 100 has been installed.

As illustrated in figures 6 and 7 the mounting bracket 150 attaches to a tubular handle 155 affixed to the rear of the CRRT monitor 15 to hold the blood warmer 20 in place. A horizontally

oriented recess 160 in the rear of the blood warmer 20 receives a mounting arm 165 of the mounting bracket 150. A retainer screw 170 secures and retains the mounting arm 165 in the recess 160. The mounting arm 165 is affixed perpendicularly to a cylindrical pivot pin 175 which fits slidingly and rotatably into a vertically oriented pivot hole 180 in a clamp block 185. The clamp block 185 inter-fits with and cooperates with a clamp 190 to secure the clamp block 185 and clamp 190 around the tubular handle 155, oriented so that the mounting arm 165 is above the clamp block 185 and extending horizontally, and with the pivot pin 175 oriented vertically. The clamp 190 is secured to the clamp block 185 by two screws 195 and an alignment pin 200.

Thus attached to the CRRT monitor 15 the mounting arm 165 and blood warmer 20 can be swiveled in a horizontal plane. A spring knob 205 is affixed to, and passes through, the mounting arm 165 and cooperates with a plurality of holes 210 in a top surface of the clamp block 185 to selectively retain the mounting arm 165 and blood warmer 20 in one of a plurality of angular positions in the horizontal plane, including the position for installation of the extension line 100 and thermal sleeve 125 and the operating and connection position.

The control portion 30 of the blood warmer 20 has a microprocessor to operate the electric heating element and to control the temperature of the heat exchanger section 25. A control panel 130 on the control portion 30 has a visual display panel 135 and a plurality of input and indicating devices 140. The control portion 30 controls the temperature at the heat transfer surface of the heat exchanger section 25 of the blood warmer 20 to an operator selected set point value. The operator may select a set point value 37° C, 39° C, or 41° C. By establishing the highest allowable set point value for the surface temperature of the heat exchanger section 25 of the blood warmer 20 at 41° C, the maximum desirable warmed blood temperature of 42° C will not be exceeded in normal operation of the blood warmer

20. If the temperature of the surface of the heat exchanger section 25 exceeds 42.5° C the blood warmer 20 over temperature indicator on the control panel 130 will be activated.

The invention has been described by reference to a preferred embodiment, it being understood that the invention is not limited to the described embodiment. The present

5 invention is defined by the spirit and scope of the following claims.

## CLAIMS

1. A continuous renal replacement therapy system comprising:  
a continuous renal replacement therapy monitor having a venous pressure  
transducer, a detector for protecting against air embolism; and a venous line clamp; and  
5 a blood warmer attached to the continuous renal replacement therapy monitor.
2. The system of claim 1 further comprising:  
a disposable tubing set adapted for engagement with the continuous renal  
replacement therapy monitor, comprising:  
a first venous line;  
10 a second venous line;  
a separable connector pair intermediate the first venous line to the  
second venous line;  
a third venous line;  
a sample access site intermediate the second venous line and the third  
15 venous line;  
a fourth venous line; and  
venous pressure pod intermediate the third and forth venous lines;  
wherein  
said fourth venous line is adapted to be received by and cooperate with the  
20 detector for protecting against air embolism and the venous line clamp.
3. The system of claim 2 further comprising:  
an extension line adapted to be received by and cooperate with the blood  
warmer and having a first end and a second end, each end having one half of a connector pair  
adapted to interconnect with the halves of the separable connector pair of the disposable

tubing set when separated, whereby the extension line is intermediate the first and second venous lines.

4. The system of claim 1 further comprising:

a disposable tubing set adapted for engagement with the continuous renal

5 replacement therapy monitor, comprising:

a first venous line;

a third venous line;

a sample access site intermediate the first venous line and the third  
venous line;

10 a fourth venous line; and

venous pressure pod intermediate the third and forth venous lines;

wherein

said fourth venous line is adapted to be received by and  
cooperate with the detector for protecting against air embolism and the venous line clamp;

15 and

said first venous line is adapted to be received by and  
cooperate with the blood warmer.

5. A disposable tubing set adapted for engagement with the continuous renal  
replacement therapy monitor having a blood warmer, comprising:

20 a first venous line;

a second venous line;

a separable connector pair intermediate the first venous line to the second  
venous line;

a third venous line;

a sample access site intermediate the second venous line and the third venous line;

a fourth venous line; and

a venous pressure pod intermediate the third and forth venous lines.

5           6.    The disposable tubing set of claim 5 further comprising:

an extension line adapted to be received by and cooperate with the blood warmer and having a first end and a second end, each end having one half of a connector pair adapted to interconnect with the halves of the separable connector pair of the disposable tubing set when separated, whereby the extension line is intermediate the first and second  
10   venous lines.

7.    A method of continuous renal replacement therapy comprising:

passing treated blood through a blood warmer prior to passing it though any one or more of:

a sample access site;

15           a venous pressure monitor;

an air embolism protection detector; and

a venous clamp.

8.    The method claim 7 wherein the venous blood is passed through the blood warmer prior to passing it through:

20           the air embolism protection detector; and

the venous clamp.

9.    The method claim 8 wherein the venous blood is further passed through the blood warmer prior to passing it through the sample access site.

10.   The method of claim 9 wherein the venous blood is further passed through the  
25   blood warmer prior to passing it through the venous pressure monitor.

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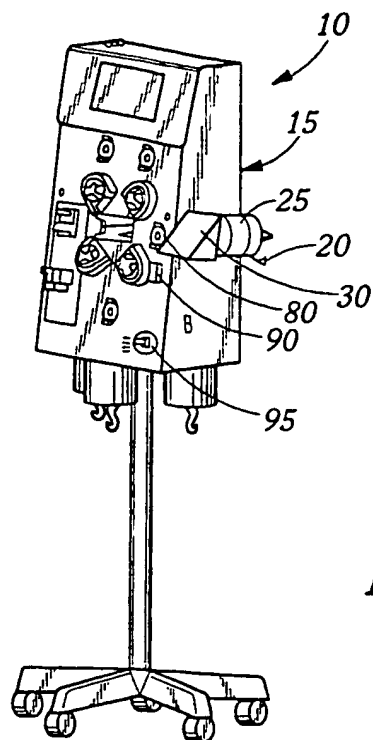


Figure 1

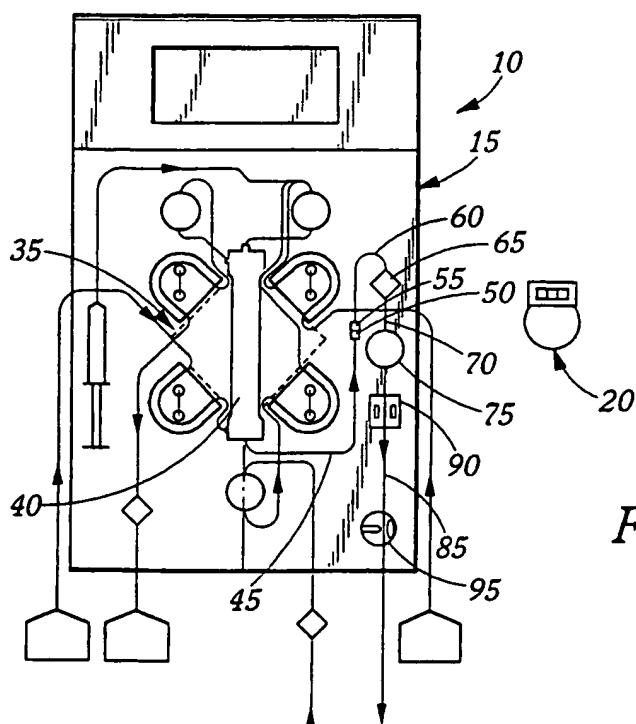
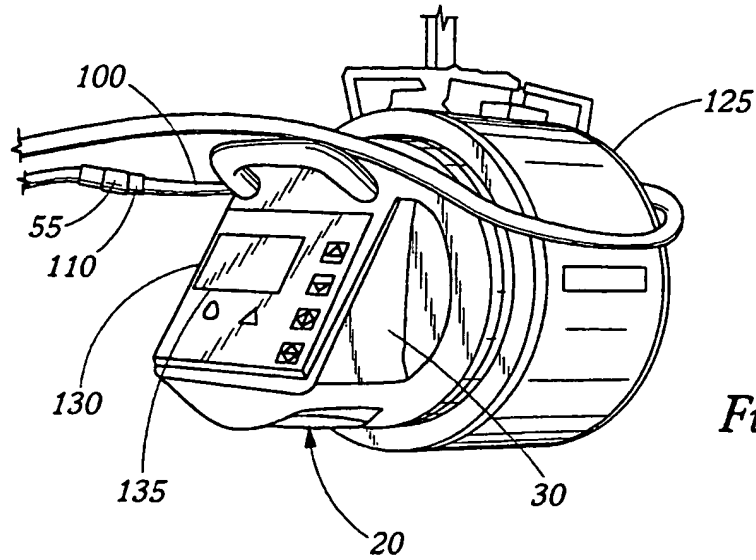
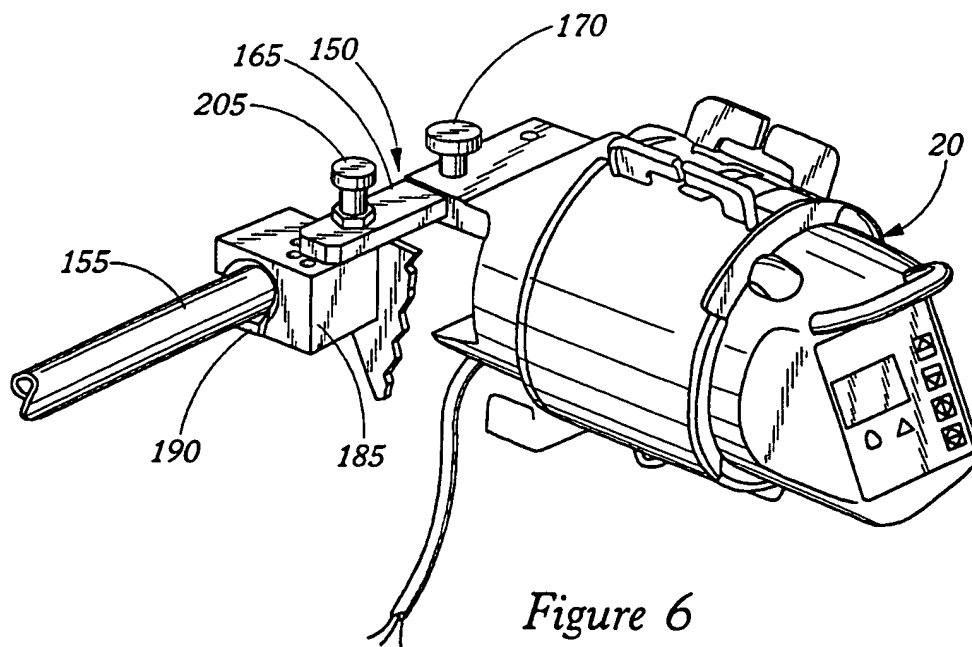
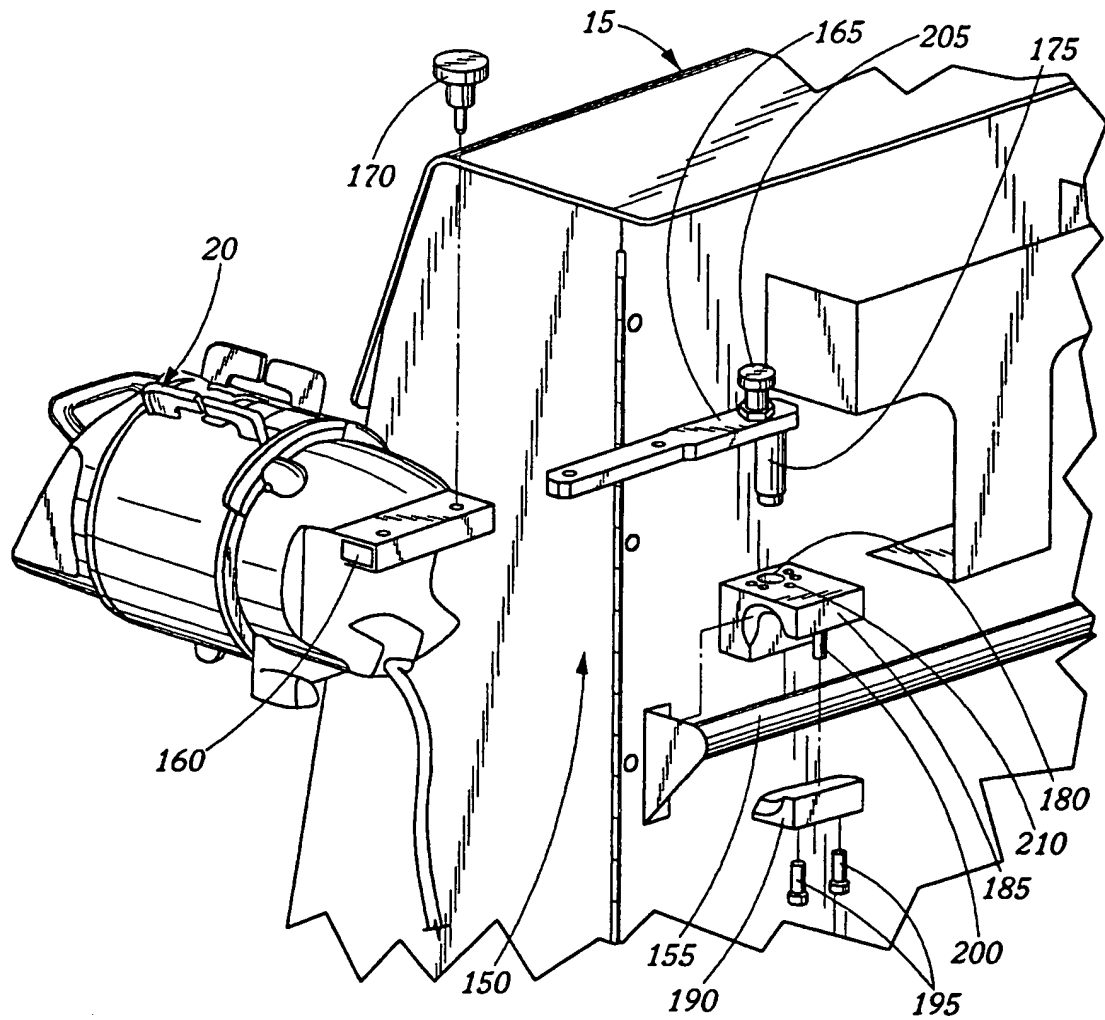


Figure 2

*Figure 5**Figure 6*

*Figure 7*